REMARKS

I. Preliminary Remarks

Claims 1 and 4 have been amended to incorporate the limitation of claim 3 which has now been canceled. Claim 14 has been amended to recite the step of separating bound from unbound tracer and has also been amended to depend from claim 17 which recites the feature of a tracer. New claims 19 and 20 have been presented which recite the method of claim 1 further comprising a step of separating bound tracer from unbound tracer (claim 19) and a kit comprising a detergent, a cyclodextrin sequestrant for the detergent, and a specific binding partner for the analyte (claim 20). These claims are supported by the disclosure (see Example 3, page 43 which discloses an assay for Interleukin-6 which does not require the use of a tracer) and do not introduce new matter.

II. Outstanding Rejections

Claims 1-14 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to distinctly claim the subject matter of the invention.

Claims 1-4, 8-11, and 13-14 stand rejected under 35 U.S.C. §103(a) as being obvious over Cook (Research Focus 1(7): 287-94, 1996) (hereinafter "Cook (1)") in view of Lundin *et al.* (U.S. 5,558,986) (hereinafter "Lundin").

Claims 1 and 15-18 stand rejected under U.S.C. §103(a) as being unpatentable over Cook (1) in view of Lundin, and in further view of Cook (WO 94/26413) (hereinafter "Cook (2)").

III. Patentability Arguments

A. The Rejections Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn

The rejection of claims 1-14 under 35 U.S.C. §112, second paragraph, may properly be withdrawn in light of the foregoing amendments made to claims 1 and 14 to more clearly recite the subject matter of the invention.

In view of the aforementioned amendment, the rejection of claims 1-14 under 35 U.S.C. §112 (second paragraph) should properly be withdrawn.

B. The Rejections Under 35 U.S.C. §103(a) Should Be Withdrawn

The rejections of claims 1-4, 8-11, and 13-14 under 35 U.S.C. §103(a) over Cook (1) in view of Lundin should be withdrawn in light of the forgoing amendments and for the following reasons. First, independent claim 1 has been amended to specify that the sequestrant is a cyclodextrin and there is no teaching in the cited art or elsewhere that a cyclodextrine be used as a sequestrant for cell lysis agents in specific binding assays.

In particular, as cyclodextrins are known complexing agents, their effective use in assays which involve specific binding reactions, such as immunoassays or competitive protein binding assays, would not have been predictable at the time of the present invention. Indeed, those of ordinary skill in the art would have expected that such potent complex forming agents would have interfered with the components of such an assay to the extent that the formation of a partner-analyte complex would have been severely inhibited. The fact that the cyclodextrins do not inhibit the highly specific binding reactions carried out by practice of the present invention is a surprising result.

While Lundin teaches the use of cyclodextrins as a sequestrant, that teaching is in the context of an assay which does not involve specific binding assays as recited by Applicant's claims. Instead, Lundin teaches the use of cyclodextrins in an assay wherein the intracellular component to be measured (ATP) acts as a co-factor for the luciferase enzyme catalysed reaction with luciferin to produce light. Lundin neither discloses nor suggests that the same reaction components could be used for specific binding assays.

Moreover, Lundin appears to hint at the potential complexing problems inherent in the use of certain types of cyclodextrins (Col. 7, lines 52-60) where the problem is overcome by increasing the amount of the complexed agent (D-Luciferin). While this problem can be overcome in an enzyme assay where the complexed agent is not the intracellular agent to be measured, the use of a similar solution would not have been applicable in the present invention as the agent being complexed would predictably be one of the intracellular components to be measured. In view of this, it would appear that the teaching of Lundin (that of the use of a cyclodextrin sequestrant in firefly luciferase enzyme assays) would not be expected by the skilled person to be applicable to specific binding assays. Indeed, those of skill in the art, when faced with knowledge of Lundin's teaching, would not have attempted a specific binding assay using a complexing agent as strong as cyclodextrin as a sequestrant.

CONCLUSION

In light of the foregoing amendments and remarks, it is believed that claims 1-20 are in condition for allowance and a notice thereof is respectfully requested. Should the Examiner wish to discuss any further matter of form or substance, she is encouraged to contact undersigned attorney at the telephone number listed below.

Respectfully submitted,

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